REMARKS

This responds to the Office Action dated on November 26, 2007.

No claims are amended, no claims are canceled, and no claims are added. Thus, claims 1-60 are currently pending in this application. Of these 60 pending claims, claims 29-60 are currently being considered, and claims 1-28 stand withdrawn from consideration.

§102/§103 Rejection of the Claims

Claims 29-43, 45-56 and 58-60

Claims 29-43, 45-56 and 58-60 were rejected under 35 U.S.C. § 102(b) as being anticipated by Kramer et al. (U.S. Patent Application Publication 2002/0133198, "Kramer"), or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Kramer. In the alternative, claims 29, 36-41, 49 and 54 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kramer. Applicant respectfully traverses the rejection for as least the following reasons.

The Office Action cites FIGS. 1-7, paragraph 19, lines 12-22, paragraph 39, lines 4-18 and paragraph 41, lines 12-17 in Kramer for recording "data including data indicative of whether the left ventricle cardiac site was paced at the predetermined time interval with respect to the cardiac event at the second cardiac site." Applicant respectfully traverses. None of the cited FIGS. 1-7 depict recording of data indicative of whether the left ventricle cardiac site was paced, as recited (i.e. verifying the LV was paced when it was supposed to be paced). The cited portion of paragraph 19 refers to collecting patient data, including lead position and current device settings such as lower rate limit, AV-delay values and LV-offset values. However this information does not include or suggest data indicative of whether the left ventricle cardiac site was paced, as recited. The LV-offset refers to time between pacing the right ventricle and the left ventricle (Kramer at paragraph 19, lines 19-22), which is different than data indicative of whether the left ventricle cardiac site was paced at the predetermined time interval with respect to the cardiac event at the second cardiac site. The cited portion of paragraph 39 refers to a max dP/dt algorithm (peak left ventricular pressure change) for optimizing pacing. However this section does not include or suggest recording data indicative of whether the left ventricle cardiac site was paced, as recited. The cited portion of paragraph 41 refers to providing biventricular

pacing using an offset value. Once again, this section does not include or suggest recording data indicative of whether the left ventricle cardiac site was paced, as recited. The recording and display of this data is used in CRT therapy, as recited in the present subject matter.

In FIG. 6 of Kramer for example, elements 648 and 656 display and print out data. However, there is no teaching or suggestion that the data includes data indicative of whether the left ventricle cardiac site was paced, as recited. In paragraph 37 cited by the Office, Kramer is measuring pressure with respect to time. However, the type of data is not the same as data indicative of whether the left ventricle cardiac site was paced at a particular time, as recited.

In addition, the Office Action states, at page 3, last paragraph, that "algorithms inherently trend data samples because they are constantly comparing, sensing, recording, processing, etc. various signals and data, based on various activities in the heart, to generate the best combination of results for achieving the desired optimum treatment." Applicant respectfully traverses. Applicant respectfully submits that the Examiner has not provided a *prima facie* case to support the alleged inherency, and thus the Kramer reference fails to show or fairly suggest the claimed subject matter. "To serve as an anticipating when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991). "This modest flexibility in the rule that 'anticipation' requires that every element of the claims appear in a single reference accommodates situations where the common knowledge of technologists is not recorded in the reference; that is, where technological facts are known to those in the field of the invention, albeit not known to judges." *Id.* at 1269. "[The inherent disclosure] must be necessarily present and a person of ordinary skill in the art would recognize its presence." *Crown Operations Intl. v. Solutia, Inc.*, 289 F.3d 1367, 1377 (Fed. Cir. 2002). Applicant respectfully submits that not every algorithm "trends data samples." Some cardiac algorithms deal strictly with ventricular pressure or blood volume, irrespective of time, and thus cannot be said to "trend" data as that term is used in the recited subject matter. Thus, a person of ordinary skill in the art would not recognize that the use of algorithms makes "trending data"

necessarily present. Therefore, Applicant respectfully asserts that Kramer does not disclose trending of data as claimed.

In paragraph 17 of the Office Action, it states that "Kramer discloses the essential features of the claimed invention as described above except not explicitly data trends, time associated with recorded data, and trend samples of data. However, it is well known in the art to include data trends, time associated with recorded data, and trend samples of data to yield the predictable results of optimizing pacing delay between two or more sites within the heart by trending a stream of data to characterize a patient's status and to show worsening and/or improving condition with respect to the paced heart." Applicant respectfully traverses. This is a conclusory statement and does not support the legal conclusion of obviousness. "Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007) citing *In re Kahn*, 441 F.3d 977, 988 (CAFC 2006). To facilitate review, this analysis should be made explicit. *Id.* In the present case, Applicant respectfully asserts that one of skill in the art would not have included data trends, time associated with recorded data, and trend samples of data with Kramer's selection of cardiac algorithms. Kramer does not at all refer to or suggest trending of any data, much less the specific data (whether the LV was paced at a particular time) recited.

Therefore, with respect to claim 29, the Office has not shown in the cited portions of the cited references, among other things, an implantable cardiac rhythm management (CRM) device including a controller adapted to control processing of the sensed signals and recording of data to the memory, the data including data indicative of whether the left ventricle cardiac site was paced at the predetermined time interval with respect to the cardiac event at the second cardiac site, a communication circuit adapted to transmit the recorded data to an external device for presentation of data trends useful to assess an efficacy of the prescribed CRT where the presentation of data trends includes presentation of recorded data and time associated with the recorded data, as recited in the claim.

Claims 30-43 and 45-48 depend, either directly or indirectly, on claim 29 and are believed to be in condition for allowance with claim 29.

Additional reasons for allowance are found in the dependent claims. With respect to claim 36, the Office has not shown nor even asserted the controller is adapted to trend samples of data indicative of whether the left ventricle cardiac site was paced at the predetermined time interval with respect to the cardiac event at the second cardiac site, including to trend N samples per unit time, as recited in the claim. With respect to claim 37, the Office has not shown nor even asserted the controller adapted to trend samples of data indicative of whether the left ventricle cardiac site was paced at the predetermined time interval with respect to the cardiac event at the second cardiac site, including to trend N samples per unit time until a predetermined change occurs in delivered CRT, and then trend M samples per unit time, as recited in the claim. With respect to claim 38, the Office has not shown nor even asserted the controller adapted to trend samples of data indicative of whether the left ventricle cardiac site was paced at the predetermined time interval with respect to the cardiac event at the second cardiac site, including to trend N samples per unit time until a predetermined threshold is reached related to delivered CRT, and then trend M samples per unit time, and then trend M samples per unit time, as recited in the claim. With respect to claim 39, the Office has not shown nor even asserted the controller adapted to trend samples of data indicative of whether the left ventricle cardiac site was paced at the predetermined time interval with respect to the cardiac event at the second cardiac site, including to trend N samples per unit time until a predetermined event occurs, and then trend M samples per unit time, as recited in the claim. With respect to claim 40, the Office has not shown nor even asserted the controller adapted to trend samples of data indicative of whether the left ventricle cardiac site was paced at the predetermined time interval with respect to the cardiac event at the second cardiac site, including to trend M samples per unit time after initiation of a trigger selected from a group consisting of: a predetermined change in delivered CRT, a predetermined threshold related to delivered CRT, and a predetermined event, as recited in the claim.

With respect to claim 49, the Office has not shown in the cited portions of the cited references, among other things, a system with a CRM device and a programmer, the CRM device including a set of interface channels adapted to provide the prescribed CRT, wherein at least one of the channels is adapted to receive sensed cardiac signals from at least one of the plurality of electrodes and a controller adapted to communicate with the set of interface channels and the

memory, the controller adapted process sensed cardiac signals and to record data to the memory of the CRM device, the data including data indicative of whether the left ventricle cardiac site was paced at the predetermined time interval with respect to the cardiac event at the second cardiac site, as recited in the claim. Claims 50-53 depend directly on claim 49 and are believed to be in condition for allowance with claim 49.

With respect to claim 54, the Office has not shown in the cited portions of the cited references, among other things, a system with a CRM device and a programmer, the CRM device including a set of interface channels adapted to provide the prescribed CRT, wherein at least one of the channels is adapted to receive sensed cardiac signals from at least one of the plurality of electrodes, and a controller adapted to communicate with the set of interface channels and the memory, the controller adapted record data to the memory of the CRM device, the data including data indicative of whether the left ventricle cardiac site was paced at the predetermined time interval with respect to the cardiac event at the second cardiac site, as recited in the claim. Claims 55, 56, and 58-60 depend directly on claim 54 and are believed to be in condition for allowance with claim 54.

Reconsideration and allowance of claims 29-43, 45-56, and 58-60 are respectfully requested.

§103 Rejection of the Claims

Claims 44 and 57

Claims 44 and 57 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kramer. Applicant respectfully traverses the rejection for as least the following reasons.

As stated above with respect to independent claims 29 and 54, Applicant respectfully asserts that Kramer does not anticipate the subject matter recited in claims 29 and 54, as recited. Claims 44 and 57 depend either directly or indirectly on claims 29 and 54, and are believed to be allowable for the reasons provided with respect to claims 29 and 54.

Since all the elements of the claims are not found in the reference, Applicant assumes that the Examiner is taking Official Notice of the missing elements. Applicant respectfully objects to the taking of Official Notice with a single reference obviousness rejection and, pursuant to

M.P.E.P. § 2144.03, Applicant respectfully traverses the assertion of Official Notice and requests that the Examiner cite references in support of this position.

Reconsideration and allowance of claims 44 and 57 are respectfully requested.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (715) 824-5144 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 26 day of February 2008.

NATE GANDOR

Name

Signature